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(71) Applicant: I-FLOW CORPORATION [US/US]; 20202 Windrow Drive, Lake Forest, CA 92630 (US).

(72) Inventors: KUST, Richard; 24051-F Hollyoak, Aliso Viejo, CA 92656 (US). WERSCHMIDT, Gary; 21905 Heatheridge Drive, Yorba Linda, CA 92887 (US). PORTER, William; 3442 Celinda Drive, Carlsbad, CA 92008 (US). KEAHY, Robert; 341 Wildrose, San Antonio, TX 78209 (US). AURIN, Gary; 19 Massier Lane, Foothill Ranch, CA 92610 (US). MASSENGALE, Roger; 28 Harveston, Mission Viejo, Ca 92692 (US).

(74) Agents: KLEIN, Howard, J. et al.; Klein, O'Neill & Singh, 2 Park Plaza, Suite 510, Irvine, CA 92614 (US).

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WO 03/017854 A1

(54) Title: APPARATUS FOR DELIVERING A VISCOUS LIQUID TO A SURGICAL SITE

(57) Abstract: Apparatus (10) for delivering a viscous liquid to a surgical site employs a conventional syringe (20) having a barrel (22) and a plunger (30) movable axially within the barrel from a withdrawn position to an inserted position. The apparatus includes an internally-threaded sleeve (42) and a substantially cylindrical actuation element (44). The sleeve is configured to receive the plunger in its withdrawn position, and has an open proximal end and a distal end slot (54) configured for receiving the syringe barrel therethrough. The actuation element has an externally-threaded distal portion (48) dimensioned to screw into the proximal end (46) of the sleeve, and a plunger seat (62), at the distal end of the actuation element, that bears against the plunger and that pushes the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve.

APPARATUS FOR DELIVERING A VISCOUS LIQUID TO A SURGICAL SITE

CROSS REFERENCE TO RELATED APPLICATIONS

Not Applicable

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

The present invention relates to an apparatus for delivering a viscous liquid material to a surgical site within the body of a human or an animal. More specifically, it relates to an apparatus for controllably delivering bone cement to a site within a bone that has been surgically prepared to receive the cement.

Many procedures in orthopedic surgery require a predetermined quantity of bone cement to be delivered to a site within a bone that has been surgically prepared to receive the cement. For example, surgery to correct certain spinal injuries or deformities requires a hole to be drilled or bored in a vertebra, and then the hole is filled with bone cement. This is accomplished by filling a syringe with bone cement, and then delivering the cement to the site via a cannula attached to the syringe by a length of flexible tubing.

Because the cement is quite thick and viscous, delivering the cement from the syringe requires a great deal of effort applied to the syringe plunger. Thus, both strength and dexterity are required on the part of the surgeon performing the procedure.

It would thus be an improvement over the current state of the art to provide a mechanism that would facilitate the delivery of bone cement and like materials by making it easier to express the material from the syringe.

SUMMARY OF THE INVENTION

Broadly, in one aspect, the present invention is an apparatus for delivering a viscous liquid to a surgical site, comprising a syringe having a barrel and a plunger movable axially within the barrel from a withdrawn position to an inserted position, and a syringe actuation device, wherein the syringe actuation device comprises (1) a hollow, internally-threaded sleeve configured to receive the plunger in its withdrawn position, the sleeve having an open proximal end and a distal end opening configured for securing the syringe barrel; and (2) a substantially cylindrical actuation element having (a) an externally-threaded distal portion dimensioned to screw into the proximal end of the sleeve, and (b) a plunger seat, at the distal end of the actuation element, that bears against the plunger and that pushes the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve.

In another aspect, the invention is a syringe actuation device for receiving and holding a pre-filled conventional syringe having a barrel containing a measure of liquid and a plunger that is axially movable into the barrel for expressing the contents therefrom, the device comprising a sleeve for securing the pre-filled syringe with the plunger in a withdrawn position and an actuation element that screws into the sleeve so as to push the plunger into the barrel to express the liquid from the syringe.

In a specific preferred embodiment, the actuation device comprises an internally-threaded hollow sleeve with an open proximal end, and a substantially cylindrical actuation element with an externally-threaded distal portion that threads into the open proximal end of the sleeve. The actuation element includes a transverse (i.e., perpendicular to the actuation element axis) plunger seat at its distal end. The sleeve has a longitudinal opening parallel to its axis for receiving the extended plunger of a pre-filled syringe, and a distal end wall portion with an opening or slot through

which the barrel of the syringe extends. Also, in the specific preferred embodiment, the proximal portion of the actuation element may be configured as an enlarged-diameter gripping element that is configured to facilitate actuation by increasing the mechanical advantage when the actuation element is screwed into the sleeve.

In use, the actuation element is backed out of the sleeve a sufficient distance in the proximal direction to allow a pre-filled syringe to be installed in the sleeve through the longitudinal opening. The barrel of the syringe being pre-filled with a measured volume of liquid, the plunger of the syringe is in its extended or withdrawn position. The outlet tip of the syringe is connected to one end of a fluid conduit, such as a length of flexible tubing, the other end of which may be coupled to an injection needle or a cannula. As the actuation element is threaded into the sleeve, the plunger seat bears against the plunger to push the plunger distally into the barrel until it reaches its fully inserted position, corresponding to the delivery of the measured volume of liquid from the barrel.

As will be appreciated that the threaded coupling between the actuation element and the sleeve allows the actuation element to be turned as a screw within the sleeve and to advance against the plunger with the mechanical advantage provided by a screw mechanism. This screwing action, in turn, allows the user more easily to apply sufficient force to the plunger to express a highly viscous liquid (e.g., bone cement) from the barrel. Furthermore, a greater degree of control can be used in actuating the plunger. For example, stopping the plunger at precise positions within the barrel, so as to express the contents of the barrel in desired increments, is greatly facilitated. These and other advantages of the invention will be more fully understood from the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an apparatus for delivering a viscous fluid to a surgical site, in accordance with a preferred embodiment of the present invention, the apparatus comprising a syringe and a syringe actuation device;

Figure 2 is a side elevational view, partially in section, of the apparatus of Figure 1, showing the syringe and the actuation element of the syringe actuation device in their respective positions prior to actuation of the syringe and resultant delivery of its contents;

Figure 3 is a transverse cross-sectional view taken along line 3 - 3 of Figure 2;

Figure 4 is a transverse cross-sectional view taken along line 4 - 4 of Figure 2;

Figure 5 is a longitudinal cross-sectional view taken along line 5 - 5 of Figure 2;

Figure 6 is a longitudinal cross-sectional view, similar to that of Figure 5, but showing the syringe and the actuation element of the syringe actuation device in their respective positions after actuation of the syringe and the delivery of its contents;

Figure 7 is a transverse cross-sectional view taken along line 7 - 7 of Figure 5;

Figure 8 is a transverse cross-sectional view taken along line 8 - 8 of Figure 5; and

Figure 9 is an end elevational view of the proximal end of the syringe actuation device, taken along line 9 - 9 of Figure 6.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, an apparatus 10 for delivering a viscous liquid to a surgical site is shown, in accordance with a preferred

embodiment of the invention. The apparatus 10 comprises a standard, conventional syringe 20 and a novel syringe actuation device 40. The syringe 20 comprises a barrel 22 that may be filled with a predetermined volume (typically, for example, 10cc or 20cc) of a liquid. In the present invention, the liquid is likely to be a highly viscous liquid, and, in particular, bone cement, but the invention is not limited to any specific type or viscosity of liquid.

The distal end of the barrel 22 tapers down to a distal outlet portion 24, which may be internally threaded (at 25) for coupling to a convention Luer fitting (not shown) at one end of a length of flexible tubing 26 (Fig. 2). The other end of the tubing 26 is typically coupled to needle or cannula (not shown) for introducing the liquid expressed from the syringe 20 to a surgical site (such as a bone, in the case of bone cement) within a patient's body. The proximal end of the barrel 22 is open and is surrounded by a peripheral flange 28.

The syringe 20 has a plunger 30 that is installed for axial movement within the barrel 22 between a withdrawn position (Figures 1, 2, and 5) and an inserted position (Fig. 6). The proximal end of the plunger 30 is advantageously configured as a flattened thumb rest 32, while the distal end of the plunger 30 is attached to a piston 33 sized for a sliding frictional engagement against the interior wall surface of the barrel 22.

The syringe actuation device 40 comprises a substantially cylindrical hollow sleeve 42 and a substantially cylindrical plunger actuation element 44 that is dimensioned to fit within the sleeve 42. The sleeve 42 has an open proximal end and internal threads 46, while the actuation element 44 has comprises a substantially tubular inner member 47a coaxially disposed within a substantially cylindrical outer member 47b. The outer member 47a has a distal portion 48 that is externally threaded to mate with the internal threads 46 when the actuation element 44 is inserted into the open

proximal end of the sleeve 42.

The sleeve 42 has a longitudinal opening 50 parallel to its axis for receiving the extended plunger 30 of a pre-filled syringe 20 (as will be described below), and a distal end wall 52 with a distal slot 54 that is contiguous with the longitudinal opening 50, and that is dimensioned to receive the syringe barrel 22. The longitudinal opening 50 extends proximally from the distal end slot 54 at least half the length, and preferably about two-thirds to about three-quarters the length of the sleeve 42. Extending distally from the distal end wall 52 is a trough-like barrel securing member 56 that communicates with the distal end slot 54. The barrel securing member 56 is configured to hold the syringe barrel 22 with a friction fit, and thus has an inside diameter that is approximately the same as the outside diameter of the syringe barrel 22. A removable insert 58 may provided in the barrel securing member 56 to reduce the inside diameter of the barrel securing member 56 to accommodate a smaller syringe barrel 22. Thus, for example, the barrel securing member 56 without the insert 58 may be dimensioned to hold a 20cc syringe, while the insert 58 may be installed if a 10cc syringe is to be used.

Attached to the distal end of the inner member 47a of the actuation element 44 is a distal end cap that comprises a distally-extending peripheral rim 60 surrounding a substantially circular plunger seat 62. The rim 60 and the plunger seat 62 define a receptacle or recess 64 that is dimensioned to receive the thumb rest 32 at the proximal end of the syringe plunger 30. The plunger seat 62 may optionally be formed with one or more distally-extending protrusions 63 against which the thumb rest 32 seats.

The outer member 47b of the actuation element 44 has a proximal portion 66 that is advantageously of an enlarged diameter to provide a convenient hand grip. To this end, it may also be formed with

longitudinal ridges 68 to provide a non-slip gripping surface. The proximal portion 66 may be internally threaded for the attachment of an externally-threaded proximal end cap 70.

In use, a syringe 20, pre-filled with a measured volume of a liquid (such as bone cement) contained in the barrel 22, is installed within the sleeve 42 through the longitudinal opening 50. The syringe barrel 22 being filled, the plunger 30 is in its withdrawn (proximal) position, extending proximally from the proximal end of the barrel 22. The barrel 22 of the syringe 20 extends through the distal end slot 54 of the sleeve 42, and it is snapped into place in the barrel securing member 56, which may be fitted with the insert 58 (as shown) or not, depending on the size (outside diameter) of the barrel. The barrel flange 28 is seated against the interior surface of the distal end wall 52 of the sleeve 42. The actuation element 44 may, at this point, be inserted into the proximal end of the sleeve 42 and threaded distally into the sleeve until the thumb rest 32 of the plunger 30 is received within the receptacle 64 in the distal end cap of the actuation element 44 and is seated against the plunger seat 62. Thus, as shown in Figures 1, 2, and 5, the apparatus 10 is ready for use to express the liquid contents of the barrel 22 out of the outlet tip 24 of the syringe 20, and to the surgical site through the conduit 26 and a needle or cannula (not shown) that is installed in the site.

To express the contents of the barrel, the actuation element 44 is threaded further distally within the sleeve 42, thereby pushing the plunger 30 distally, toward its inserted position within the barrel 22, through the engagement between the plunger seat 62 and the thumb rest 32. As shown in Figure 6, this process may be continued until the plunger 30 is in its fully inserted (distal) position, at which point the entire volume of liquid contained within the barrel 22 has been emptied therefrom. It will be appreciated that this process can be interrupted at any desired position(s)

of the plunger to express a part of the contents, or to express the contents in desired increments.

The screw mechanism action of the actuation element 44 within the sleeve 42 provides a marked mechanical advantage that facilitates the dispensing of highly viscous liquids, such as bone cement, from the syringe 20. Furthermore, the partial or incremental dispensing of the syringe contents can be more easily controlled, by means of the screw mechanism, as compared with manually actuating the plunger by pressure applied directly by the user's thumb. Contributing to the control is the characteristic that nearly the entire length of the barrel 22 is visible, both the proximal portion carried within the barrel securing member 56, and the distal portion that extends distally from the barrel securing member. In addition, syringe actuation device 30 can easily be re-used. The empty syringe can easily be removed and replaced with a new syringe.

While a preferred embodiment of the invention has been described herein, it will be appreciated that a number of modifications and variations will suggest themselves to those skilled in the pertinent arts. For example, while it is a particular advantage of the preferred embodiment that it employs a conventional syringe, it may be modified for use with any number of specialized syringes that either are now available or that may be devised in the future. Also, the specific structure of the actuation element 44 described herein is exemplary only, and many alternative structures and configurations (such as, for example, a unitary structure instead of the multipart structure) may suggest themselves. Such modifications, as well as others that may suggest themselves, are considered to be within the spirit and scope of the present invention, as defined in the claims that follow.

WHAT IS CLAIMED IS:

1. Apparatus for delivering a liquid to a surgical site, comprising:

a syringe having a barrel and a plunger that is axially movable within the barrel between a withdrawn (proximal) position and an inserted (distal) position, the plunger having a proximal end; and

a syringe actuation device, comprising:

a hollow, internally-threaded sleeve configured to receive the plunger in its withdrawn position, the sleeve having an open proximal end and a distal end opening configured for securing the syringe barrel; and

a substantially cylindrical actuation element having an externally-threaded distal portion dimensioned to screw into the proximal end of the sleeve, and a plunger seat positioned in the distal portion of the actuation element to bear against the plunger so as to push the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve.

2. The apparatus of Claim 1, wherein the sleeve has a distal end slot dimensioned to receive the syringe barrel, and a longitudinal opening extending from the distal end slot toward the proximal end and dimensioned to receive the syringe plunger in its withdrawn position.

3. The apparatus of Claim 2, wherein the distal end slot of the sleeve is in a distal end wall, and wherein the sleeve further comprises:

a syringe barrel securing member extending distally from the distal end wall and communicating with the distal end slot, the securing member having an inside diameter dimensioned to receive the syringe barrel.

4. The apparatus of Claim 3, further comprising:

a removable insert configured to fit within the barrel securing member to reduce the inside diameter of the barrel securing member to accommodate a smaller syringe barrel.

5. The apparatus of Claim 1, wherein the actuation element has a proximal portion configured as an enlarged-diameter hand grip.

6. The apparatus of Claim 1, wherein the actuation element has a longitudinal axis and includes a recess in its distal and, and wherein the plunger seat comprises a surface in the recess that is transverse to the axis of the actuation element.

7. The apparatus of Claim 6, wherein the plunger has a proximal end configured as a flattened thumb rest, and wherein the recess is configured to receive the thumb rest.

8. A device for actuating a syringe, wherein the syringe includes a barrel and a plunger movable axially within the barrel from a withdrawn (proximal) position to an inserted (distal) position, the device comprising:

a hollow, internally-threaded sleeve configured to receive the plunger in its withdrawn position, the sleeve having an open proximal end and a distal end opening configured for securing the syringe barrel; and

a substantially cylindrical actuation element having an externally-threaded distal portion dimensioned to screw into the proximal end of the sleeve, and a plunger seat positioned in the distal portion of the actuation element to bear against the plunger so as to push the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve.

9. The device of Claim 8, wherein the sleeve has a distal end slot dimensioned to receive the syringe barrel, and a longitudinal opening extending from the distal end slot toward the proximal end and dimensioned to receive the syringe plunger in its withdrawn position.

10. The device of Claim 9, wherein the distal end slot of the sleeve is in a distal end wall, and wherein the sleeve further comprises:

a syringe barrel securing member extending distally from the distal end wall and communicating with the distal end slot, the securing member having an inside diameter dimensioned to receive the syringe barrel.

11. The device of Claim 10, further comprising:

a removable insert configured to fit within the barrel securing member to reduce the inside diameter of the barrel securing member to accommodate a smaller syringe barrel.

12. The device of Claim 8, wherein the actuation element has a proximal portion configured as an enlarged-diameter hand grip.

13. The device of Claim 8, wherein the actuation element has a longitudinal axis and includes a recess in its distal and, and wherein the plunger seat comprises a surface in the recess that is transverse to the axis of the actuation element.

14. The device of Claim 13, wherein the plunger has a proximal end configured as a flattened thumb rest, and wherein the recess is configured to receive the thumb rest.

15. A device for actuating a syringe, wherein the syringe includes a

barrel and a plunger movable axially within the barrel from a withdrawn (proximal) position to an inserted (distal) position, the device comprising:

a hollow, internally-threaded sleeve having an open proximal end, a distal end slot configured to receive the syringe barrel therethrough, and a longitudinal opening extending from the distal end slot toward the proximal end and dimensioned to receive the plunger in its withdrawn position; and

a substantially cylindrical actuation element having a longitudinal axis, an externally-threaded distal portion dimensioned to screw into the proximal end of the sleeve, and a plunger seat positioned in the distal portion of the actuation element and comprising a surface transverse to the longitudinal access and configured to bear against the plunger so as to push the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve.

16. The device of Claim 15, wherein the distal end slot of the sleeve is in a distal end wall, and wherein the sleeve further comprises:

a syringe barrel securing member extending distally from the distal end wall and communicating with the distal end slot, the securing member having an inside diameter dimensioned to receive the syringe barrel.

17. The device of Claim 16, further comprising:

a removable insert configured to fit within the barrel securing member to reduce the inside diameter of the barrel securing member to accommodate a smaller syringe barrel.

18. The device of Claim 15, wherein the actuation element has a proximal portion configured as an enlarged-diameter hand grip.

19. The device of Claim 18, wherein the plunger has a proximal end configured as a flattened thumb rest, and wherein the plunger seat is defined within a recess configured to receive the thumb rest.

20. A method of delivering a viscous liquid to a surgical site, comprising the steps of:

(A) providing a syringe having a barrel filled with the viscous liquid, the syringe having a plunger movable axially within the barrel between a withdrawn (proximal) position and an inserted (distal) position;

(B) installing the filled syringe into a hollow, internally-threaded sleeve configured to receive the plunger in its withdrawn position, the sleeve having an open proximal end and a distal end opening configured for securing the syringe barrel;

(C) providing a substantially cylindrical actuation element having an externally-threaded distal portion dimensioned to screw into the proximal end of the sleeve, and a plunger seat positioned in the distal portion of the actuation element to bear against the plunger so as to push the plunger axially toward its inserted position in the barrel as the actuation element is threaded into the sleeve; and

(D) inserting the distal portion of the actuation element into the proximal end of the sleeve and threading the actuation element into the sleeve so as to bring the plunger seat to bear against the plunger, thereby pushing the plunger from its withdrawn position toward its inserted position to express the liquid from the syringe barrel.

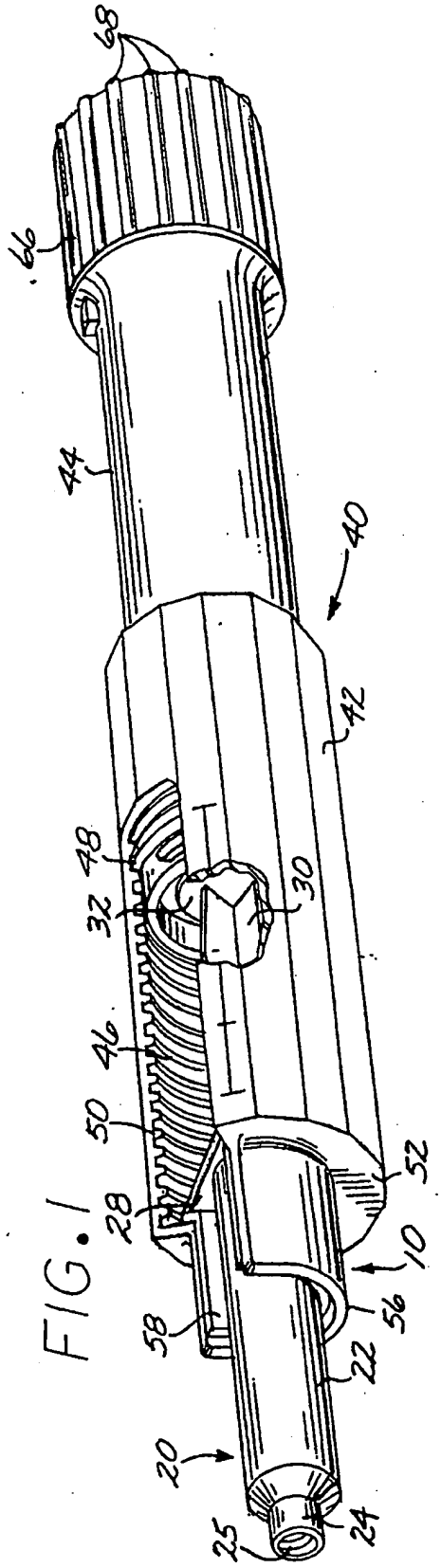
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FIG. 1

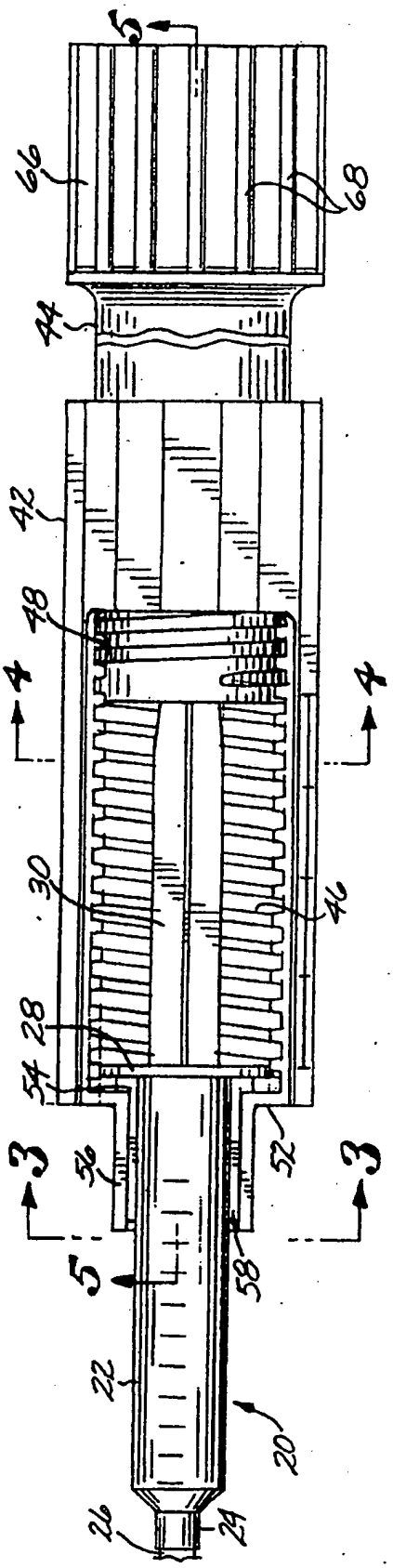
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FIG. 2

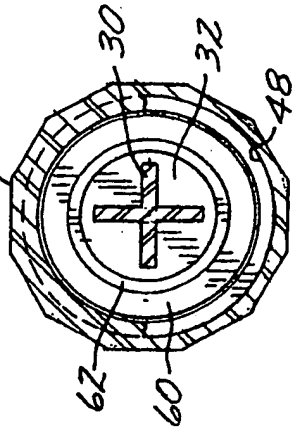

FIG. 4

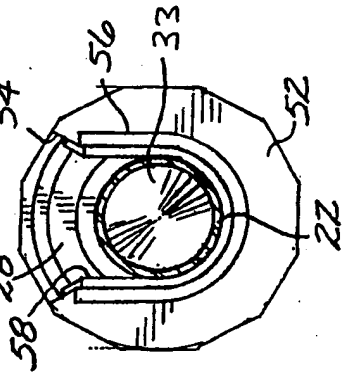

FIG. 3

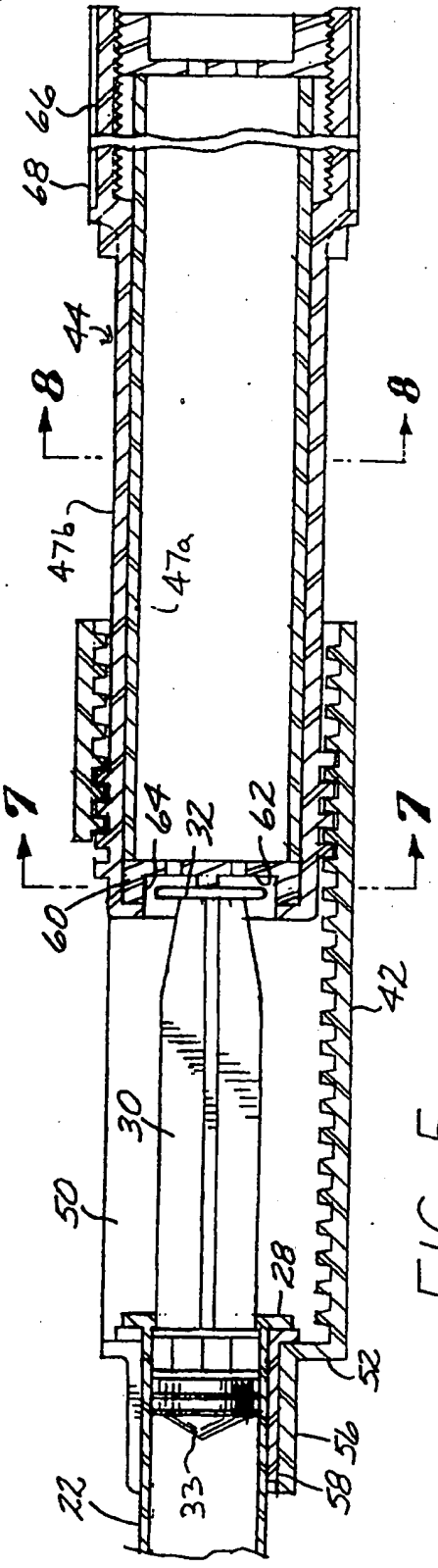

FIG. 5

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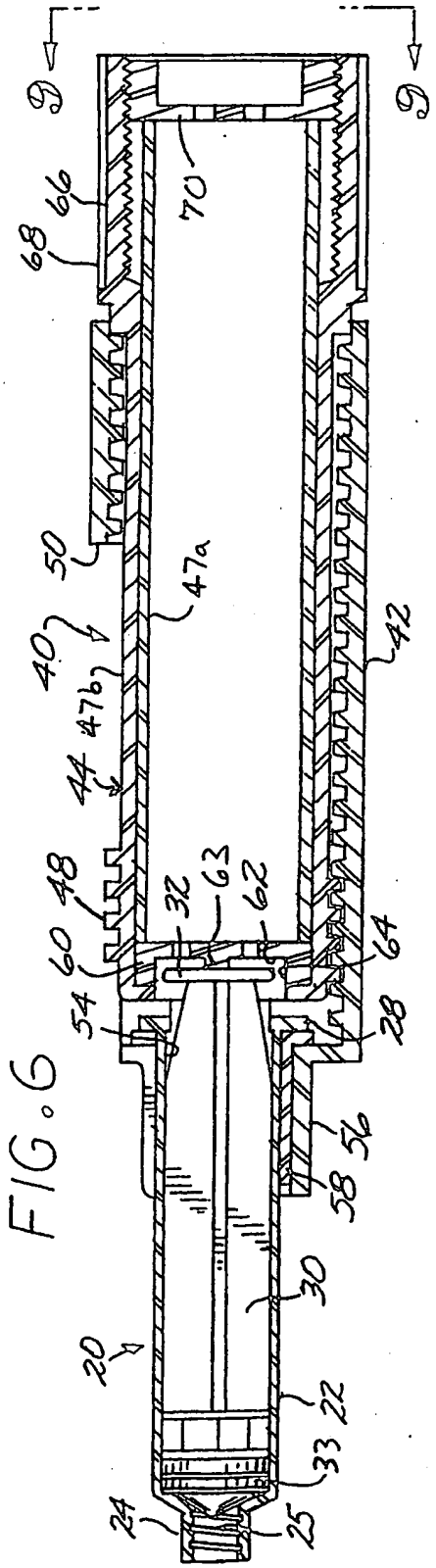

FIG. 6

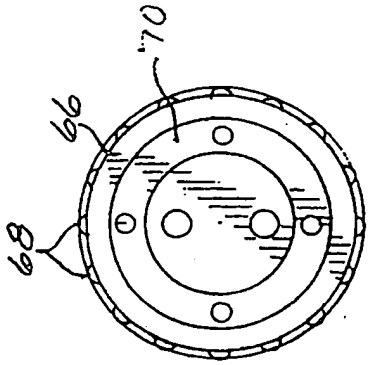

FIG. 9

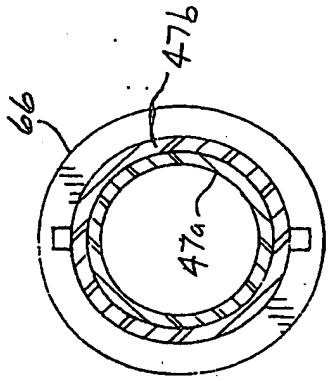

FIG. 8

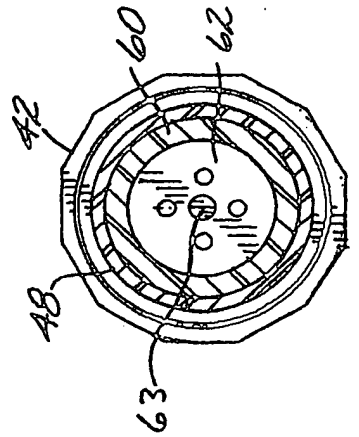

FIG. 7

INTERNATIONAL SEARCH REPORT

Interr ial Application No
PCT/US 02/26325

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/58 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 599 315 A (C.J.MCPHEE) 4 February 1997 (1997-02-04) figures 1,2,4 ---	1-19
X	US 5 454 793 A (G.LEVANDER AND O.LJUNGQUIST) 3 October 1995 (1995-10-03) column 4, line 10 - line 19; figures 1,2 ---	1,5,8, 12,15, 16,18,19
X	WO 99 65597 A (ORTHOFIX) 23 December 1999 (1999-12-23) page 3, line 4 - line 18; figure 3 ---	1,5-8, 12-15
X	US 5 456 388 A (J.P.HONSTEIN AND R.J.BARNES) 10 October 1995 (1995-10-10) column 8, line 59 -column 10, line 4; figures 13-15 --- -/--	1-3,5, 8-10,12

[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
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Date of the actual completion of the international search	Date of mailing of the international search report
4 December 2002	10/12/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Nice, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interr ial Application No
PCT/US 02/26325

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 266 463 A (B.N.HENDY) 3 November 1993 (1993-11-03) page 4, line 9 - line 10; figure	1,5-8, 12-14
X	US 4 312 343 A (H.H.LEVEEN) 26 January 1982 (1982-01-26) abstract; figures 1,2	1,5,8,12

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

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Box I Observation where c rtain claims were found unsearchabl (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

.....mation on patent family members

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